

K061071  
1 of 2

AUG 29 2006

**Section I 510(k) Summary of Safety and Effectiveness**

**Applicant:**

Atom Medical Inc  
Iwakata Bldg 3<sup>rd</sup> Floor 3-18-15, Hongo  
Tokoyo, Bunkyo-ku 1130033 Japan  
Registration No: In process

**Contact Person:**

Neoforce Group  
35 Commerce Drive  
Ivyland, Pa 18974

Mary Staniewicz  
Ph 215-672-6800  
Fax 215-672-1123

**Device trade/proprietary name:**

V-808 Atom Transcapsule

**Device common/usual/classification name:**

Neonatal Transport Incubator

**Classification:**

General Hospital  
21 CFR 880.5410  
Infant Incubator, FPL, Class II

Anesthesiology  
21 CFR 870.2700  
Oximeter, DQA, Class II

**Performance Standards:**

None applicable

**Predicate Device:**

K941106 TI500 Transport Incubator  
K990966 Masimo Set Pulse Oximeter

## Device Description

This product consists of a hood section, a mattress platform section, a middle deck section, a conditioning chamber section, an operation section and a pedestal section. It is equipped with an incubator air temperature control function to circulate the air containing the heat energy generated by the heater attached to the conditioning chamber inside the hood by means of a fan in order to maintain the incubator air temperature at a fixed level, an oxygen supply function to deliver oxygen into the inner hood from outside, and a function to determine and display the oxygen concentration of the enclosed compartment covered by the hood. It is further equipped with a function to measure and display the skin temperature of the neonate, as well as a pulse oximeter function to determine oxygen saturation and pulse rate non-invasively.

It is a transport incubator, wherein said functions are intended to be used in treatment, procedures and observation of low-birth-weight and sick neonates, allowing provision of heat to the neonate when the body temperature is low.

## Intended Use

The V-808 Atom Transcapsule is a neonatal transport incubator. The incubator is a device with a transparent hood intended to contain a premature infant or a neonatal infant within the compartment covered by said hood and intended to safely convey the infant accommodated in that compartment, providing the infant with isolated environment from ambient air where temperature – controlled air is supplied. The V-808 also provides oxygen monitoring and supply as well as an integrated pulse oximetry capability.

## Description of Modifications

The difference between the V-808 and the TI500 predicate device is the SpO<sub>2</sub> feature. The Pulse Oximetry SpO<sub>2</sub> is provided by Masimo and is also a currently marketed device. The V-808 combines two medical device technologies on to one platform, the neonatal transport incubator and pulse oximeter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 29 2006**

Atom Medical Incorporated  
C/O Ms. Mary Staniewicz  
Chief Financial Officer  
NeoForce Group Incorporated  
35 Commerce Drive  
Ivyland, Pennsylvania 18974

Re: K061071  
Trade/Device Name: V-808 Atom Transcapsule  
Regulation Number: 880.5410  
Regulation Name: Neonatal Transport Incubator  
Regulatory Class: II  
Product Code: FPL  
Dated: August 11, 2006  
Received: August 14, 2006

Dear Ms. Staniewicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K061071  
181

## Section A SMDA Requirements

### A.1 Indication for Use Statement

510(k) Number:

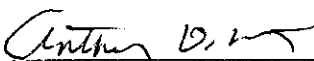
Device Name: V-808 Atom Transcapsule

Indications for Use:

The V-808 Atom Transcapsule is a neonatal transport incubator. The incubator is a device with a transparent hood intended to contain a premature infant or a neonatal infant within the compartment covered by said hood and intended to safely convey the infant accommodated in that compartment, providing the infant with isolated environment from ambient air where temperature – controlled air is supplied. The V-808 also provides oxygen monitoring and supply as well as an integrated pulse oximetry capability.

This device is not intended for home use.

This is a prescription device.



(Signature Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K961471

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Please do not write below this line continue on another page if needed)  
Concurrence of CDRH, Office of Device Evaluation (ODE)